



Scientific Committee on Health and Environmental Risks

SCHER

Risk Assessment Report on Aluminium fluoride

Environmental Part

CAS No.: 7784-18-1  
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The SCHER adopted this opinion at its 25<sup>th</sup> plenary on 9 September 2008

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### SCHER

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[http://ec.europa.eu/health/ph\\_risk/risk\\_en.htm](http://ec.europa.eu/health/ph_risk/risk_en.htm)

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## 1. BACKGROUND

Council Regulation 793/93 provides the framework for the evaluation and control of the risk of existing substances. Member States prepare Risk Assessment Reports on priority substances. The Reports are then examined by the Technical Committee under the Regulation and, when appropriate, the Commission invites the Scientific Committee on Health and Environmental Risks (SCHER) to give its opinion.

## 2. TERMS OF REFERENCE

On the basis of the examination of the Risk Assessment Report the SCHER is invited to examine the following issues:

- (1) Does the SCHER agree with the conclusions of the Risk Assessment Report?
- (2) If the SCHER disagrees with such conclusions, it is invited to elaborate on the reasons.
- (3) If the SCHER disagrees with the approaches or methods used to assess the risks, it is invited to suggest possible alternatives.

## 3. OPINION

### 3.1 General comments

The RAR on aluminium fluoride (AlF<sub>3</sub>) is of good scientific quality and is based on information available in open literature and on data supplied by industry. This RAR is atypical as it is a targeted assessment of AlF<sub>3</sub> focussing only on the atmospheric compartment. The reason for this is that although the EU risk assessment on hydrogen fluoride (HF) (2001) identified local risks to the atmospheric and aquatic compartments for a number of HF facilities (production, use and/or processing), the regional exposure assessment was not performed. This was due to the fact that, quote: *'also other F-containing High Production Volume Chemicals and so-called unintentional sources, would significantly contribute to regional emissions of HF into the atmosphere (and water)'*. It was therefore decided to also perform a risk assessment on AlF<sub>3</sub> and CaF<sub>2</sub> (fourth priority list) to obtain a more balanced regional exposure assessment of fluoride. It was decided to make a targeted RA for these substances focussing only on the atmospheric compartment. A number of arguments for not addressing the water compartment are given in the AlF<sub>3</sub> RAR. These include, quote: *'(1) F-emissions from the AlF<sub>3</sub> industry are in general lower than the emissions; (2) no information was received that fluorides constitute a water problem at the regional scale'*.

SCHER, based on the limited information given in the RAR on AlF<sub>3</sub>, is of the opinion that these statements do not justify why this RA was limited to the atmospheric compartment.

Recognising the targeted nature of the RAR, SCHER notes that this risk assessment adhered to a large extent to TGD procedures. SCHER could not verify the exposure calculations as not all relevant information was available to the committee.

Although SCHER agrees with conclusions presented in the RAR, it does have some concerns about the interpretation of the RCRs obtained for some of the exposure scenarios.

## 3.2 Specific comments

### 3.2.1 Exposure assessment

The total amount of AlF<sub>3</sub> within the EU in the year 2000 was 63,826 tonnes (production + import-export). The main use of AlF<sub>3</sub> (> 99.6%) is as a temperature- and pH regulator and as a solubility enhancer in the production process of aluminium.

The RAR states that the total amount of HF released to the atmospheric compartment in the EU during production and industrial use of AlF<sub>3</sub> is 1.2 and 2,464 t/y, respectively (in 2000).

For the terrestrial compartment, PEC local values for AlCl<sub>3</sub> production were based on atmospheric deposition only. The contribution of STP sludge applied on agricultural fields was not taken into account as, in the RAR, it is considered to be negligible. SCHER is of the opinion that evidence should be provided that this latter assumption is correct. The PEC<sub>local</sub> calculated for the production plant with the highest emission to air was 0.1 mg/kg. The PEC<sub>local</sub> for downstream use, calculated using the atmospheric PEC (0.2 µg/m<sup>3</sup>) and a realistic deposition rate, was 0.035 mg F/kg. The calculated PEC<sub>regional</sub> for the soil compartment was 0.04 mg F/kg.

PEC<sub>local</sub> values for the atmospheric compartment were calculated with EUSES after adjustment of some of the defaults. These modifications were aimed to make the calculations more realistic and are based on detailed information provided by industry. SCHER agrees with this modified approach.

The PEC<sub>local</sub> values for the different production sites vary from 0.003 to 0.063 µg/m<sup>3</sup>. For the industrial/professional use of AlF<sub>3</sub>, PEC<sub>local</sub> values range from 0.65 to 27 µg/m<sup>3</sup>.

Comparison between the predicted and measured levels indicated that the latter are approximately 3 to 6 times lower than the measured data. Plausible explanations are given from the observed differences.

The RAR gives an overview of the fluoride emissions to air in the EU in 2001 based the data in the European Pollutant Emission Register. Given a total emission of 11,945 tonnes/y, a PEC<sub>regional</sub> of 0.20 µg/m<sup>3</sup> for the atmosphere was calculated. SCHER could not verify these calculations through the lack of detailed information in the RAR. This calculated PEC<sub>regional</sub> seems to be in good agreement with the mean measured concentration established for the Netherlands.

### 3.2.2 Effect assessment

Although some limited aquatic toxicity data are presented, no PNEC was derived for this compartment as this RAR was 'targeted' at assessing the risks for the atmospheric and terrestrial compartment.

The PNECs for the terrestrial and atmospheric compartment used in the RAR are the values taken – without revision – from the risk assessment on HF (RAR HF, 2001). These PNEC are: 11 mg/kg for the soil compartment and 0.2 µg/m<sup>3</sup> for the atmospheric compartment (plant-air).

In the CSTEE opinion (2000) on the HF RAR a number of concerns are expressed on the type and quality of data used to derive the PNECs for both compartments. As these same values are used here, the scientific validity of these PNECs is also questioned by SCHER.

The fluoride NOECs used for assessing the non-compartment effects on the food chain were also taken – without revision – from the HF RAR.

### 3.2.3 Risk characterisation

SCHER is of the opinion that the title 'European Union Risk Assessment Report: Aluminium Fluoride' might be misleading as this title suggests that the risks to all

compartments were assessed. This was not the case in this RAR. It is SCHER's opinion that the targeted nature of this risk assessment should be clearly reflected in the title (front page) and/or clearly stated in the Introduction (and several other places) and Conclusion section of this report.

The following conclusions by SCHER should be considered in the light of the concerns expressed (1) on the PNEC values used and (2) on the committee's inability to verify the presented exposure calculations.

- For AIF<sub>3</sub> production and down-stream users, PEC/PNEC values < 1 for the terrestrial compartment are derived. Conclusion (ii)<sup>1</sup> is drawn. This conclusion is also proposed for the regional scale. SCHER supports these conclusions.
- For the atmospheric compartment, local PEC/PNEC values at production sites vary from 1 to 1.4. The RAR, however, justifies a conclusion (ii) *'in view of the limited contribution of local air concentration to the exceeding of the PNEC'*. SCHER is concerned that despite a RCR > 1, conclusion (ii) is proposed in the RAR. The deviation from normal practice may affect objectivity and consistence of the conclusions presented in other RARs.
- The regional PEC/PNEC for the atmospheric compartment is ≤1 and conclusion (ii) is drawn. SCHER supports this conclusion.
- For down-stream use of AIF<sub>3</sub> at the local scale, PEC/PNEC values range from 4 to 135. The RAR proposes conclusion (iii). SCHER supports this conclusion.
- Local air concentrations around primary Al production sites exceed the atmospheric PNEC for live stock. As such, the RAR proposes conclusion (iii) for non-compartment specific effects relevant to the food chain. SCHER supports this conclusion.

#### 4. LIST OF ABBREVIATIONS

EUSES	European Union System for the Evaluation of Substances
NOEC	No Observed Effect Concentration
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
RA	Risk Assessment
RAR	Risk Assessment Report
RCR	Risk Characterisation Ratio
STP	Sewage Treatment Plant
TGD	Technical Guidance Document

#### 5. REFERENCES

European Union Risk Assessment report on Hydrogen Fluoride (2001). 1<sup>st</sup> Priority List, Volume 8. EC 793/93.

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<sup>1</sup> According to the *Technical Guidance Document on Risk Assessment – European Communities 2003*:

- conclusion i): *There is a need for further information and/or testing;*

- conclusion ii): *There is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already;*

- conclusion iii): *There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.*